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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,112	10/03/2003	Edward R. Kraft	ERK/001	2257
1473 7590 04/10/2007 FISH & NEAVE IP GROUP ROPES & GRAY LLP 1211 AVENUE OF THE AMERICAS NEW YORK, NY 10036-8704			EXAMINER MITRA, RITA	
			ART UNIT	PAPER NUMBER
			1656	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/10/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/679,112

Applicant(s)

KRAFT E.

Examiner

Rita Mitra

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-53 and 62-96 is/are pending in the application.
- 4a) Of the above claim(s) 28-30, 32-34, 62-79 and 81-96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-27, 31, 35-53 and 80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/6/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicants' election with traverse of Group II, drawn to claims 24-53 in response to office action mailed October 16, 2006, filed on December 15, 2006 is acknowledged. Applicant's species election of drugs (claim 27), comprising cytotoxics (claim 31), gelling agent comprising cellulose derivatives (claim 35) is acknowledged. Claims 1-23 and 54-61 have been cancelled. Claims 27, 28, 31-38 have been amended. New claims 62-96 have been added. Applicants submit that claim 24 is generic as all of the claims provided in group II include each and every feature of claim 24. Further Applicants submit that claims 25-53 and 62-96 depend from claim 24. The arguments have been considered but not found persuasive because claims 62-79 and 81-96 are directed to the following patentably distinct species of the claimed invention: biologically active substance, drug, gelling agent. The species are independent or distinct because they are structurally and functionally divergent and would require separate non-overlapping searches. Therefore, claims 62-79 and 81-96 are not currently under examination.

The requirement is still deemed proper and is therefore made FINAL.

Claims 28-30, 32-34, 62-79 and 81-96 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Therefore, claims 24-27, 31, 35-53 and 80 are currently under examination.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 31, the phrase 'comprises a cytotoxic' renders the claim indefinite because it is unclear whether the limitation cytotoxic is a drug or what?

***Claim Rejections - 35 U.S.C § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-27, 31, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Jiang et al. (Jiang et al., Journal of Controlled Release, vol. 19, pp. 41-58, 1992, IDS Ref.).

Jiang et al. teach enhanced photodynamic killing of target cells by either monoclonal antibody (MoAb) or low density lipoprotein (LDL) mediated delivery system. The reference shows that the photosensitizer benzoporphyrin derivative monoacid ring A (BPD) could be covalently bound to a MoAb (5E8) via a modified polyvinyl alcohol (PVA). Further Jiang et al. demonstrated that both BPD-5E8 conjugate and BPD-LDL mixtures exhibited enhanced photodynamic killing on target cells. Further Jiang et al. teach that internalized BPD-5E8 and BPD-LDL displayed much higher cytotoxicity than that of surface associated BPD-5E8 and BPD-LDL, respectively. The reference describes the preparation of BPD-5E8 and BPD-LDL solution, using aqueous and organic solvent. Further Jiang et al. describe treating of A549 and M-1 cell lines with BPD-5E8 and BPD-LDL followed by irradiating with sixteen 100 tungsten bulbs (400-1200 nm). The light was filtered through a 4 cm thick water filter with circulating cool water (see abstract, page 43, col. 1, page 44, col. 2, page 47, col. 1-2, page 48, col. 2 to page 49 col. 1). Jiang et al. suggest that this improved delivery of PS may result in the possible detection and treatment of small, unidentified lesions (page 56, col. 1, last paragraph).

Thus, claims 24-27, 31, 39, 40 are anticipated by Jiang et al.

***Claim Rejections- 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-27, 31, 35-53 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang et al. (Jiang et al., Journal of Controlled Release, vol. 19, pp. 41-58, 1992, IDS Ref.), in view of Huang et al. (Journal of Photochemistry and Photobiology, A: Chemistry, vol 108, pp. 229-233, 1997, IDS Ref.) and Kreindel et al. (U.S. 6,387,089 B1, IDS Ref.).

Application of Jiang et al. is the same as in the above rejection of claims 24-27, 31, 39 and 40. However, Jiang et al. does not describe a gelling agent and a photocatalytic agent with a band gap energy and which is a rutile form of titanium dioxide.

Huang et al. disclose the photocatalytic killing effect of ultrafine TiO<sub>2</sub> particles (UFP TiO<sub>2</sub>) and its mechanism of action on malignant cells (human U937 cells). The reference describes the preparation of TiO<sub>2</sub> colloidal solution, using organic solvent isopropanol and water. Further Huang et al. describe treating of U937 cells with TiO<sub>2</sub> followed by irradiating with 500 W high pressure Hg lamp. A UV pass filter was used to obtain a light wavelength between 300-400 nm (see abstract, page 229, Introduction col. 1, paragraph 1, page 230, col. 1, paragraph 2). Huang et al. suggest that this could be used for the treatment of superficial tumors in an organ appropriate for light exposure such as the skin and oral cavity trachea (page 232, col. 2, last paragraph).

Huang et al. does not explicitly disclose the use of pulsed incoherent light as claimed in the instant invention. Huang et al. does not describe a gelling agent in the solution.

Kreindel et al. disclose a method and apparatus for treating skin including applying pulsed light to the skin for heating and shrinking collagen within the skin, thereby reviving the elasticity of the collagen and of the skin. The method also includes protecting the epidermis and outer layers of the skin by cooling the epidermis and outer layers of the skin by applying a transparent substance such as ice, gel or crystal. Further Kreindel et al. disclose control of temperature distribution within the skin by controlling the delay between the time the coolant is applied and the time the light is applied, by controlling the pulse duration and applying multiple pulses, and by filtering the light and controlling the radiation spectrum, wherein the spectrum includes light having a wavelength in the range of 500-2000 nm., wherein the pulsed light may be incoherent such as that produced by a flashlamp (see abstract and col. 2, lines 13-49) or a near infrared pulsed laser (see col. 7, lines 26-30).

Therefore, it would have been obvious to the person having ordinary skill in the art to combine the teachings of Jiang with the teaching of Huang and Kreindel because Kreindel's pulsed incoherent light source have the parameters suitable for implementing the invention such as light radiation should penetrate into a tissue in a millimeter depth; and applying a long pulse or a train of short pulses cools down the epidermis faster (see col. 5, lines 27-32; and lines 66-67 bridging col 5 and lines 1-5, col.6). Also, it would have been obvious to the person having ordinary skill in the art to use photocatalytic agent of Huang such as TiO<sub>2</sub> because TiO<sub>2</sub> when absorbs light with energy greater than its band gap, electrons in the valence band are excited to the conduction band, creating electron-hole pairs (page 229, col. 1, paragraph 1 and page 232 under 'discussion').

### ***Conclusion***

No claims are allowed.

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***Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm.

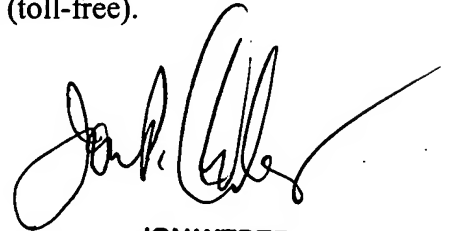
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita Mitra, Ph.D.

March 18, 2007



**JON WEBER  
SUPERVISORY PATENT EXAMINER**